



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

ze

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,607	04/21/2004	Carl M. Mendel	BBC-128/1	5201

34213 7590 07/19/2007
ABBOTT BIORESEARCH
100 RESEARCH DRIVE
WORCESTER, MA 01605-4314

EXAMINER

ROYDS, LESLIE A

ART UNIT	PAPER NUMBER
----------	--------------

1614

MAIL DATE	DELIVERY MODE
-----------	---------------

07/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/828,607

Applicant(s)

MENDEL ET AL.

Examiner

Leslie A. Royds

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1 and 3-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>05 February 2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1 and 3-11 are presented for examination.

Applicant's Amendment filed May 31, 2007 in response to the notice of non-compliant amendment dated January 22, 2007 has been received and entered into the present application. Accordingly, the title of the application has been newly amended to now read ---TREATMENT OF NEUROPATHIC PAIN---

Applicant's Information Disclosure Statement (IDS) filed February 5, 2007 has been received and entered into the present application. As reflected by the attached, completed copy of form PTO-1449 (one page total), the U.S. Patent and foreign patent documents have been fully considered. Applicant refers to the previously submitted copies of the cited non-patent literature in prior U.S. Patent Application No. 09/528,798. However, after a reasonable search by the Examiner, said documents could not be located and, therefore, have not been further considered.

Claims 1 and 3-11 are pending and under examination. Claims 12-13 are cancelled.

Applicant's papers and remarks, filed on May 31, 2007, have been fully considered and are persuasive in overcoming the objections to the claims and the title of the invention.

However, the Terminal Disclaimers filed on October 30, 2006 disclaiming the terminal portion of U.S. Patent No. 6,803,387 and the terminal portion of any patent granted on U.S. Patent Application No. 10/979,596 have been reviewed, but are not sufficient to overcome either rejection. Specifically, each of the Terminal Disclaimers fails to state the owner of the conflicting patent or application.

Accordingly, due to the unacceptable nature of the timely filed Terminal Disclaimers, the obviousness-type double patenting rejections are herein **maintained** and will be repeated below for clarity of the record.

Art Unit: 1614

Rejections and objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Present claim 1 is directed to a method for treating neuropathic pain comprising the step of administering to a human in need thereof a therapeutically effective amount of a compound of formula I, an enantiomer or a pharmaceutically acceptable salt thereof, in which R1 and R2 are independently H or methyl, in conjunction with a pharmaceutically acceptable diluent or carrier.

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP §2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for *Examination of Patent Applications* under the 35 U.S.C. 112.1

Art Unit: 1614

“Written Description” Requirement (“*Guidelines*”), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by “showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics,” including, *inter alia*, “functional characteristics when coupled with a known or disclosed correlation between function and structure...” *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66 Fed. Reg. at 1106 (emphasis added)). Moreover, although *Eli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

Applicant’s present claim 1 reads upon the administration of a therapeutically effective amount of “a compound of formula I”. The presence of the word “a” broadens the claim to read upon compounds of formula I *per se* or virtually any compound with any correlation, basis or relationship to formula I. In other words, the claim is not limited to only those compounds that are encompassed by formula I, but rather is broadened to read upon the administration of a therapeutically effective amount of any compound that is derived from, analogous to, or is in some way related to compounds of formula I.

Applicant discloses various compounds, such as the (+) and (-) enantiomers of N,N-dimethyl-1-[1-(4-chlorophenyl)-cyclobutyl]-3-methylbutylamine, etc. at pages 1-2 of the instant specification. Despite this disclosure, however, Applicant has failed to provide any structural characteristics, chemical formula, name(s) or physical properties that would provide adequate written description of the compounds based upon the presently claimed formula I that Applicant was actually in possession of, and intended to be used within the context of the present invention, at the time of the present invention. Accordingly, such disclosure, while noted, does not provide a teaching of what compounds other than those of formula I *per se* would be considered within the scope of the phrase “a compound of formula I” such that one of ordinary skill in the art would have been able to readily identify the scope of those compounds encompassed by the phrase “a compound of formula I” aside from those explicitly identified

Art Unit: 1614

in the instant disclosure.

While it may be construed that the fact that the compound is based or derived from formula I implies some sort of chemical or structural characteristic sufficient to fulfill the written description requirement of 35 U.S.C. 112, first paragraph, it is herein noted that Applicant has failed to describe in any certain terms the degree of derivation or structural similarity that a compound may have to the parent formula I and still be considered within the scope of those compounds intended for use by Applicant. The mere fact that the only chemical or structural characteristic of the compound is that it is based upon or derived from formula I, wherein the degree of similarity or derivation from formula I is herein undefined in the accompanying specification, is not sufficient to provide an adequate description of the genus of compounds intended by Applicant for use in the present invention. In the absence of such description, Applicant's limitation to "a compound of formula I" is not sufficiently supported by the present disclosure in such a way as to satisfy the written description requirement of 35 U.S.C. 112, first paragraph.

While it is recognized that adequate written description of a limitation is not required to be stated *in haec verba* in the specification or claims as originally filed, adequate written support for all claim limitations must arise from either an explicit or an implicit suggestion by the disclosure to show that such a concept as now claimed was actually in possession of the Applicant at the time of the invention. For the reasons provided *supra*, Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concept of "a compound of formula I".

Accordingly, the claim is considered to lack sufficient written description and is properly rejected under 35 U.S.C. 112, first paragraph.

Art Unit: 1614

Claim Rejections - 35 USC § 102 (New Grounds of Rejection)

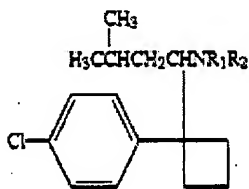
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Vargas (U.S. Patent No. 5,459,164; 1995) in light of Vinik et al. ("Diabetic Neuropathies", 1992 Dec; 15(12):1926-75; Abstract Only), cited to show a fact.

Vargas teaches methods of administering a therapeutically effective amount of compounds of the



formula , wherein R1 and R2 are independently hydrogen or methyl, or pharmaceutically acceptable salts thereof, wherein the compound is administered in conjunction with a pharmaceutically acceptable diluent or carrier, for improving the glucose tolerance of humans having non-insulin dependent diabetes mellitus (NIDDM) (abstract and col.1, lines 6-22). Vargas teaches N,N-dimethyl-1-[1-(4-chlorophenyl)cyclobutyl]-3-methylbutylamine hydrochloride and N,N-dimethyl-1-[1-(4-chlorophenyl)cyclobutyl]-3-methylbutylamine hydrochloride monohydrate as preferred compounds (col.1, lines 23-25 and 40-44) and further teaches the presence of a chiral center in the generic formula and, therefore, two possible enantiomeric forms (col.1, lines 45-50).

Vinik et al. is cited for its teaching that diabetic neuropathy, particularly painful polyneuropathy, is a common complication of diabetes (abstract). In other words, the diabetic patients suffering from concomitant painful neuropathy (i.e., neuropathic pain) are considered to be necessarily present in the population of diabetic patients taught by Vargas. Therefore, the administration of the same compound(s) as claimed (see formula *supra*) to a patient suffering from diabetes is considered to necessarily have the

Art Unit: 1614

claimed effect on treating neuropathic pain, whether recognized by the patentee or not. Products of identical chemical composition cannot exert mutually exclusive properties when administered under the same circumstances or, in the present case, the same host. Please reference MPEP §2112.

The explanation of an effect obtained when using a compound cannot confer novelty on a known process if the skilled artisan was already aware of the occurrence of the desired therapeutic effect. In other words, even if the treatment of neuropathic pain (i.e., in a diabetic patient with painful neuropathy) was not itself recognized as a pharmacological effect of administering the claimed compounds of Vargas to a patient suffering from diabetes and diabetic neuropathy, such an effect is not considered a new therapeutic application because the known treatment of diabetes mellitus, from which the painful neuropathy results, is already known in the prior art. Though mechanisms of action or new properties of a compound are not doubt important contributions to scientific and pharmaceutical development, the assessment of patentability under 35 U.S.C. 102 (or 103) is based upon the therapeutic applications and effects of the compounds, not the mechanisms or properties by which they exert such a therapeutic effect.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

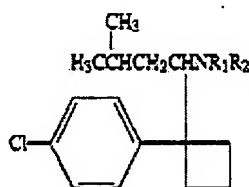
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner

Art Unit: 1614

to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 3-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vargas (U.S. Patent No. 5,459,164; 1995) in light of Vinik et al. ("Diabetic Neuropathies", 1992 Dec; 15(12):1926-75; Abstract Only), cited to show a fact, in view of Bailey et al. (WO 98/11884; 26 March 1998).

Vargas teaches methods of administering a therapeutically effective amount of compounds of the



formula , wherein R1 and R2 are independently hydrogen or methyl, or pharmaceutically acceptable salts thereof, wherein the compound is administered in conjunction with a pharmaceutically acceptable diluent or carrier, for improving the glucose tolerance of humans having non-insulin dependent diabetes mellitus (NIDDM) (abstract and col.1, lines 6-22). Vargas teaches N,N-dimethyl-1-[1-(4-chlorophenyl)cyclobutyl]-3-methylbutylamine hydrochloride and N,N-dimethyl-1-[1-(4-chlorophenyl)cyclobutyl]-3-methylbutylamine hydrochloride monohydrate as preferred compounds (col.1, lines 23-25 and 40-44) and further teaches the presence of a chiral center in the generic formula and, therefore, two different possible enantiomeric forms (col.1, lines 45-50).

Vinik et al. is cited for its teaching that diabetic neuropathy, particularly painful polyneuropathy, is a common complication of diabetes (abstract). In other words, the diabetic patients suffering from concomitant painful neuropathy (i.e., neuropathic pain) are considered to be necessarily present in the population of diabetic patients taught by Vargas. Therefore, the administration of the same compound(s) as claimed (see formula *supra*) to a patient suffering from diabetes is considered to necessarily have the claimed effect on treating neuropathic pain, whether recognized by the patentee or not. Products of identical chemical composition cannot exert mutually exclusive properties when administered under the same circumstances or, in the present case, the same host. Please reference MPEP §2112.

The explanation of an effect obtained when using a compound cannot confer novelty on a known process if the skilled artisan was already aware of the occurrence of the desired therapeutic effect. In other words, even if the treatment of neuropathic pain (i.e., in a diabetic patient with painful neuropathy) was not itself recognized as a pharmacological effect of administering the claimed compounds of Vargas to a patient suffering from diabetes and diabetic neuropathy, such an effect is not considered a new therapeutic application because the known treatment of diabetes mellitus, from which the painful neuropathy results, is already known in the prior art. Though mechanisms of action or new properties of a compound are not doubt important contributions to scientific and pharmaceutical development, the assessment of patentability under 35 U.S.C. 102 (or 103) is based upon the therapeutic applications and effects of the compounds, not the mechanisms or properties by which they exert such a therapeutic effect.

Though Vargas generically teaches the use of the individual enantiomers of the compounds of the formula described *supra*, Bailey et al. is relied upon for its teachings of specific enantiomeric compounds of the identical chemical formula as that taught by Vargas, including, but not limited to, N,N-dimethyl-1-[1-(4-chlorophenyl)-cyclobutyl]-3-methylbutylamine, N-{1-[1-(4-chlorophenyl)cyclobutyl]-3-methylbutyl}-N-methylamine, 1-[1-(4-chlorophenyl)cyclobutyl]-3-methylbutylamine (page 4, lines 4-10) and the compound N-{1-[1-(4-chlorophenyl)-cyclobutyl]-3-methylbutyl}-N,N-dimethylamine (page 2, lines 23-26). The use of any one or more of these enantiomers would have been well within the purview of, and *prima facie* obvious to, one of ordinary skill in the art at the time of the invention. Such a person would have a reasonable expectation of success in achieving the same or substantially similar therapeutic effect in accomplishing the claimed objective with any one or more of these enantiomers in view of Vargas, who expressly and unequivocally teaches the use of any enantiomeric form of the disclosed compounds for use in the disclosed methods, and further in the absence of any evidence to the contrary.

Art Unit: 1614

Double Patenting

Due to the unacceptable nature of the Terminal Disclaimers filed October 30, 2006, the following obviousness-type double patenting rejections remain proper and are herein repeated below:

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Non-Provisional Rejection

Claims 1 and 3-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,803,387.

Cancellation of claims 12-13 renders the present rejection moot over such claims.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the patent and those of the present application are not considered to be patentably distinct from each other because the patented claims clearly anticipate the present claims. The patented claims clearly provide for the treatment of neuropathic pain as it results from shingles and nerve injury comprising administering to a human in need thereof a therapeutically effective amount of a compound of formula I, which is identical to the genus of compounds presently claimed, wherein the compound is in conjunction with a pharmaceutically

Art Unit: 1614

acceptable diluent or carrier. While the patented claims are not drawn specifically to neuropathic pain in general, it remains that the claims are ultimately drawn to the same therapeutic objective, regardless of the recitation of the origin of the condition and, thus, anticipate claims to the treatment of the same disorder of any etiology. Such a situation is analogous to a genus-species relationship. The recitation of a "species", in this case, neuropathic pain associated with shingles and nerve injury, will always anticipate the "genus", in this case, neuropathic pain in general (i.e., of any etiology). Please reference MPEP §2131.02 for a discussion of genus-species situations and also *In re Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960) and *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

Accordingly, rejection of present claims 1 and 3-11 is deemed proper over claims 1-12 of U.S. Patent No. 6,803,387 as claiming obvious and unpatentable variants thereof.

Provisional Rejection

Claims 1 and 3-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-13 of copending U.S. Patent Application No. 10/979,596.

Cancellation of claims 12-13 renders the present rejection moot over such claims.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the copending claims and those of the present application are not considered to be patentably distinct from each other because the copending claims clearly anticipate the present claims. The copending claims clearly provide for the treatment of neuropathic pain as it results from diabetes and varied peripheral neuropathies comprising administering

Art Unit: 1614

to a human in need thereof a therapeutically effective amount of a compound of formula I, which is identical to the genus of compounds presently claimed, wherein the compound is in conjunction with a pharmaceutically acceptable diluent or carrier. While the copending claims are not drawn specifically to neuropathic pain in general, it remains that the claims are ultimately drawn to the same therapeutic objective, regardless of the recitation of the origin of the condition and, thus, anticipate claims to the treatment of the same disorder of any etiology. Such a situation is analogous to a genus-species relationship. The recitation of a "species", in this case, neuropathic pain associated with shingles and nerve injury, will always anticipate the "genus", in this case, neuropathic pain in general (i.e., of any etiology). Please reference MPEP §2131.02 for a discussion of genus-species situations and also *In re Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960) and *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

Furthermore, it is noted that the ultimate therapeutic objective of both the copending claims and the present claims is identical (i.e., neuropathic pain). Though the copending claims are drawn to the treatment of neuropathic pain as it results from diabetes and varied peripheral neuropathies, it remains that what is being treated as the objective of executing the method is the treatment of the neuropathic pain, not the treatment of diabetes or the varied peripheral neuropathies. As a result, the origin of the neuropathic pain does not limit the methods and, therefore, the subject matter of the present claims and that of the copending claims does not differ from one another.

Accordingly, rejection of present claims 1 and 3-11 is deemed proper over claims 2-13 of copending U.S. Patent Application No. 10/979,596 as claiming obvious and unpatentable variants thereof.

Art Unit: 1614

Conclusion

The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Please reference Chapter 91 of The Merck Manual of Diagnosis and Therapy (Sixteenth Edition, 1992; pages 1106-1125).

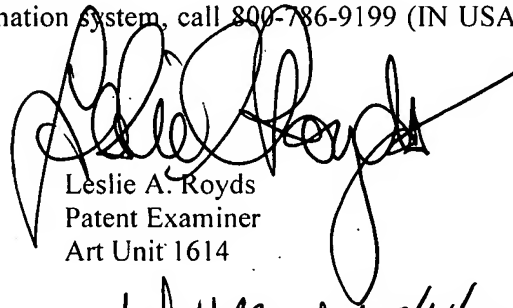
Rejection of claims 1 and 3-11 remains proper and is **maintained**.

No claims of the instant application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie A. Royds
Patent Examiner
Art Unit 1614

July 11, 2007



ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER